IN THE UNITED STATES DISTRICT COURT

FOR THE WESTERN DISTRICT OF WISCONSIN

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JUDY MARVIN, BEVERLY SCHULTZ,
PATRICIA COLLINS, ROBERT ELICK
and SANDRA CONLEY, individually and
as next friend of the ESTATE OF SHIRLEY JOHNS,

Plaintiffs,

v.

ZYDUS PHARMACEUTICALS (USA) INC. and
WYETH PHARMACEUTICALS, INC.,

Defendants.

OPINION and ORDER

15-cv-749-bbc

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Plaintiffs have brought state law claims of negligence and wrongful death against defendants Zydus Pharmaceuticals (USA) Inc. and Wyeth Pharmaceuticals, Inc. for injuries sustained by Shirley Johns, who died as a result of taking a drug commonly known as Amiodarone. Defendant Zydus Pharmaceuticals (USA) Inc. moved to dismiss the complaint on grounds that (1) plaintiffs' claims for wrongful death, gross negligence and off-label marketing are barred by the applicable statute of limitations; and (2) plaintiffs' claim that defendant was negligent per se in not providing federally-required medication guides for the Amiodarone it manufactured is impliedly preempted by the Food, Drug and Cosmetic Act, 21 U.S.C. § 337. (All further references to "defendant" will be to defendant Zydus only.)

During the course of the parties' briefing, it became apparent that they also disputed whether Wisconsin would recognize a claim of negligence per se. On April 28, 2016, I

denied defendant's motion to dismiss plaintiff's claims as barred by the statute of limitations but reserved ruling on the negligence per se claim to allow the parties to submit further briefing on the preemption and state law issues. Dkt. #71.

Having reviewed the parties' supplemental briefing, I conclude that Wisconsin would recognize a claim of negligence per se and that the claim is not subject to implied preemption. In reaching this conclusion, I have accepted as true the allegations of fact in plaintiffs' first amended complaint, dkt. #16, which I set forth in my previous order and incorporate by reference in this opinion.

OPINION

Regulations promulgated by the Food and Drug Administration require that drug manufacturers issue medication guides with certain prescribed drugs and biological products when the agency determines that (1) information is necessary to prevent serious adverse effects; (2) patients should be informed about a known serious side effect; or (3) patients' adherence to directions for the use of a product is essential to the product's effectiveness. 21 C.F.R. § 208.1. Any manufacturer who ships a container of the drug product must insure that medication guides are available for each patient receiving a prescription by providing (or providing the means to produce) a sufficient number of medication guides for authorized distributors, packers and dispensers. 21 C.F.R. § 208.24(b).

In this case, plaintiffs allege that defendant Zydus failed to provide medication guides for the Amiodarone it manufactured to any of the pharmacies from which Shirley Johns

obtained defendant's drug. As defendant points out, the Food, Drug and Cosmetics Act does not allow private litigants to enforce its provisions. 21 U.S.C. § 337(a) (enforcement proceedings "shall be by and in the name of the United States"). See also Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341, 349 n.4 (2001) ("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who [is] authorized to file suit for noncompliance with [its] provisions."). Although plaintiffs are not attempting to enforce the medication guide regulations directly, they are relying on them to establish the standard of care for their claim that defendant was negligent per se in failing to warn Johns about the side effects of Amiodarone. In other words, plaintiffs contend that defendant was negligent because it violated a federal statute related to public health and safety.

As discussed in the previous order, there is some confusion about whether the limitation on enforcement actions in § 337(a) prohibits plaintiffs from basing a negligence per se claim on defendant's alleged violation of the federal medication guide provisions. In order to bring their claim, plaintiffs must show that (1) it is not subject to implied preemption under the doctrine announced in Buckman; and (2) it meets the requirements for negligence per se claims under Wisconsin law. I will address these two issues separately.

A. Implied Preemption

In Buckman, 531 U.S. at 347, the Supreme Court held that the Food, Drug, and Cosmetic Act as amended by the Medical Devices Amendments "impliedly preempted" state law fraud claims because the claims conflicted with federal law. In that case, the plaintiffs

alleged that a manufacturer of bone screws made fraudulent representations to the Food and Drug Administration in the course of obtaining federal approval to market the screws. In dismissing their claim, the Court reasoned that the Act empowers the Food and Drug Administration to deter and punish fraud and that the "balance [of statutory objectives] sought by the [Food and Drug] Administration can be skewed by allowing fraud-on-the-FDA claims under state tort law." Id. at 348. It specifically noted that "[t]he FDA . . . has at its disposal a variety of enforcement options that allow it to make a measured response to suspected fraud," id. (citing enforcement limitation in 21 U.S.C. § 337(a)). It distinguished claims based on traditional state law tort principles that had predated the federal statute from claims for "fraud-on-the-agency" claims, that is, those in which the existence of federal requirements was a critical element. Id. at 353.

Defendant contends that permitting plaintiffs to rely on a federal regulation as a substitute for key elements of a state law cause of action (i.e., duty and breach) "effectively deputizes private plaintiffs to enforce federal law" and violates the holding in Buckman. Dkt. #74 at 4. Plaintiffs distinguish Buckman on the ground that it involved a "fraud on the agency" claim that did not exist under state law. Buckman, 531 U.S. at 347 ("[T]he relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law."). They argue that, unlike the claim in Buckman, their failure to warn claim arises under state law and falls within a field traditionally occupied by the states—the labeling of prescription drugs.

As noted in the previous order, courts have resolved the implied preemption issue in negligence per se cases in conflicting and often muddled ways, at times confusing it with the express preemption provision in 21 U.S.C. § 360(k) applicable to medical devices. Dkt. #71 at 11-12. Defendant cites a few cases in which federal district courts have held that imposing liability because the defendant violated the Food, Drug and Cosmetics Act or its regulations amounts to the private enforcement of federal law and is therefore subject to implied preemption under Buckman. E.g., Perdue v. Wyeth Pharmaceuticals, Inc., __ F. Supp. 3d.___, 2016 WL 3951091 (E.D.N.C. Jul. 20, 2016) (negligence per se claim impliedly preempted because it arose solely under federal law); Kapps v. Biosense Webster, Inc., 813 F. Supp. 2d 1128, 1151-52 (D. Minn. 2011) ("A negligence-per-se claim that is predicated on an alleged violation of the FDCA is, by definition, a claim that would give rise to liability under Minnesota law only because of the FDCA's enactment. Such a claim is preempted under Buckman."). See also Mitaro v. Medtronic, Inc., 23 Misc. 3d 1122(A), 886 N.Y.S.2d 71 (Sup. Ct. 2009), aff'd, 73 A.D.3d 1142, 900 N.Y.S.2d 899 (2010) (intentional misrepresentation and fraud claims premised on false representations to the Food and Drug Administration are impliedly preempted under Buckman). (Although defendant cites other federal and state cases for the same proposition, those cases either do not address implied preemption or dispose of the negligence per se claim on state law grounds.) In Perdue, the district court addressed the same claim at issue in this case: the allegation that a manufacturer of a generic version of Amiodarone was negligent per se under North Carolina law for failing to adhere to the medication guide requirements. Perdue,

2016 WL 3951091, at *5. The court was persuaded that implied preemption applied because North Carolina had never required the provision of medication guides. Id. at *4-6 (citing several cases holding that test for implied preemption is whether state claim would exist in absence of Food, Drug and Cosmetic Act).

Plaintiffs point out, however, that a number of federal circuit courts considering the issue have held or noted in dicta that state claims based on violations of the Food, Drug and Cosmetics Act are not impliedly preempted. McClellan v. I-Flow Corp., 776 F.3d 1035, 1041 (9th Cir. 2015) ("Where the plaintiff in Buckman alleged that the defendant made fraudulent representations *during* the market approval process, *to the FDA*, [] McClellan's requested [jury] instructions [on negligence per se] have little to do with direct regulatory interaction with the FDA."); Fulgenzi v. PLIVA, Inc., 711 F.3d 578, 586-87 (6th Cir. 2013) (failure to warn claim based on defendant's violation of federal duty to include an updated warning in its labeling of drug not impliedly preempted because claim based on traditional state tort law principles); Hughes v. Boston Scientific Corp., 631 F.3d 762, 775 (5th Cir. 2011) (allowing plaintiffs to show that defendant's violations of Food and Drug Administration regulations breached its duty to warn under state law and finding that "plaintiffs in Buckman were attempting to assert a freestanding federal cause of action based on violation of the FDA's regulations. . . [and] did not assert violation of a state tort duty."); Bausch v. Stryker Corp., 630 F.3d 546, 558 (7th Cir. 2010) (explaining that state law claim arising solely from violation of federal requirements is impliedly preempted but one alleging "breach of a well-recognized duty owed to [plaintiff] under state law" survives implied

preemption); In re Orthopedic Bone Screw Products Liability Litigation, 193 F.3d 781, 791 (3d Cir. 1999) (affirming dismissal of state law negligence claims alleging conspiracy to violate the Federal Food, Drug, and Cosmetic Act but noting in dicta that some courts have allowed plaintiffs to use federal statutory violations to prove liability for separate state tort claim). Most instructive is the decision of the Court of Appeals for the Seventh Circuit in Bausch, which is binding on this court.

Bausch involved state law negligence and product liability claims based on allegations that the defendant had manufactured a hip replacement medical device in violation of federal law. Bausch, 630 F.3d at 548. Defendant tries unsuccessfully to distinguish the case, arguing that the court of appeals held that plaintiff's claims were state law "parallel claims" that successfully threaded the gap between § 360 express preemption and implied preemption under Buckman. Bausch, 630 at 552-53, 556-57. The court of appeals specifically rejected the argument defendant is raising in this case, finding that implied preemption did not apply:

> [Defendants] extract language from Buckman to conclude that Congress clearly provided that the Food, Drug, and Cosmetic Act and the Medical Device Amendments should be "enforced exclusively by the Federal Government" and that only the FDA can enforce the regulations on which Bausch's claims are based. See id. at 352, 121 S.Ct. 1012. This argument is not convincing.
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> [T]he Buckman court specifically distinguished such "fraud-on-the-agency" claims, i.e., claims not related to a field of law that states had traditionally occupied, from claims based on state law tort principles such as in Silkwood v. Kerr–McGee Corp., 464 U.S. 238, 104 S. Ct. 615, 78 L. Ed. 2d 443 (1984), and Lohr itself. "[I]n contrast to situations implicating 'federalism

> concerns and the historic primacy of state regulation of matters of health and safety,' as in Lohr, 518 U.S. at 485 [116 S.Ct. 2240], no presumption against pre-emption obtains in this case." Id.
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> Bausch's claims, like those in Lohr, and unlike those in Buckman, are tort law claims based on manufacturing defects, not fraud on a federal agency.
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> Here, as in Lohr and as recognized in Riegel, the plaintiff claims breach of a well-recognized duty owed to her under state law—the duty of a manufacturer to use due care in manufacturing a medical device. She may do so as long as she can show that she was harmed by a violation of applicable federal law. Her claim is not impliedly preempted by federal law.

Id. at 556-58. In a recent decision, the District Court for the Eastern District of Wisconsin followed the reasoning in Bausch and held that the plaintiff could base her state claims of negligence, fraud, product liability and breach of warranty on defendant's alleged violations of federal regulations related to the promotion of an off-label use of a medical device because the claims arose from "an independent, well-recognized duty owed under state law." Garross v. Medtronic, Inc., 77 F. Supp. 3d 809, 816 (E.D. Wis. 2015).

As in Bausch and Garross, plaintiffs allege in this case that defendant violated a well-recognized state law duty to warn that is independent of federal requirements. Plaintiffs' claim is a tort law claim based on defendant's alleged failure to warn, rather than fraud on a federal agency. Accordingly, the claim is not subject to implied preemption under Buckman. I turn next to the question whether Wisconsin law allows plaintiffs to use defendant's alleged violations of the medication guide regulations as the basis of a negligence per se claim.

B. Negligence Per Se under Wisconsin Law

The Wisconsin Supreme Court has held that "[f]or the violation of a safety statute to constitute negligence per se, a plaintiff must show: (1) the harm inflicted was the type the statute was designed to prevent; (2) the person injured was within the class of persons sought to be protected; and (3) there is some expression of legislative intent that the statute become a basis for the imposition for civil liability." Tatur v. Solsrud, 174 Wis. 2d 735, 743, 498 N.W.2d 232 (1993) (citing Walker v. Bignell, 100 Wis. 2d 256, 268-69, 301 N.W.2d 447 (1981)). The state court explained that "court[s] must keep in mind that '[s]tatutes are not to be construed as changing the common law unless the purpose to effect such change is clearly expressed therein.'" Id., 174 Wis. 2d at 743-44 (quoting Kranzush v. Badger State Mutual Casualty Co., 103 Wis. 2d 56, 74, 307 N.W.2d 256 (1981)).

Defendant contends that plaintiffs cannot satisfy the third factor set forth in Tatur because § 337(a) and Buckman, 531 U.S. 341, make clear that there is no private right of action (and therefore no legislative intent that the statute become a basis for the imposition of civil liability) with respect to violations of the medication guide requirements. In support of its contention, defendant cites Cali v. Danek Medicine, Inc., 24 F. Supp. 2d 941, 953-54 (W.D. Wis. 1998), in which the plaintiff alleged a conspiracy among defendants to violate Food and Drug Administration regulations. Because Wisconsin recognizes claims for civil conspiracy only to the extent that the conspiracy resulted in the commission of an actionable tort, plaintiff had to show that the violation of the federal regulations supported a claim for negligence per se under Wisconsin law. Id. at 953. Judge John Shabaz applied the Tatur

factors and concluded that the third element was absent because there was "no explicit private right of action and no suggestion that the Act creates an implied private right of action." Id. at 954. He noted that "[f]ar from containing an expression that FDA regulations are intended to form the basis for civil liability, the law expresses the opposite intention. Violations of the FDA are enforceable only by the United States." Id. (citing 21 U.S.C. § 337(a)).

Plaintiffs point out that two district courts in the Seventh Circuit have had the opportunity to consider the holding in Cali and found it unpersuasive. In Valente v. Sofamor, S.N.C., 48 F. Supp. 2d 862, 875-76 (E.D. Wis. 1999), the court relied on Medtronic v. Lohr, 518 U.S. 470, 495 (1996), for the view that nothing in the *express* preemption provision of the Medical Device Amendments to Act, 21 U.S.C. § 360(k), prohibits states from providing a damages remedy for violations of common law duties when those duties parallel federal requirements. The court did not address § 337(a)'s prohibition on private right of actions or explain how the provision may evidence legislative intent with respect to imposing civil liability. However, it appeared to consider the enforcement limitation in its general discussion of legislative intent and it held that the prohibition was limited to federal law:

> [W]hile the law is settled that Congress did not expressly intend for the FDCA to become a basis for civil liability under federal law, "intent may be inferred from the language and the surroundings of the statute." See Johnson v. Blackburn, 220 Wis. 2d 260, 280, 582 N.W.2d 488, 497 (Ct. App.), rev. granted, 220 Wis. 2d 363, 585 N.W.2d 156 (1998). In Lohr, the Supreme Court noted that the MDA was enacted "to provide for the safety and effectiveness of medical devices intended for human use" and that the primary issue motivating the MDA's enactment was "the safety of those who use

> medical devices." 518 U.S. at 490–491, 116 S. Ct. 2240. Such clear intent that the statute's primary motivation is to protect the safety of those who use medical devices is sufficient to infer the intent of Congress that the statute be used as a basis for civil liability under state common law.

Id. at 876.

In other words, the court concluded in Valente that even though the Act does not provide an express statement regarding liability, its clear expression that the Medical Device Amendments were enacted to protect users of medical devices is sufficient under Wisconsin law to show that Congress intended to allow those provisions to provide the basis of a negligence per se claim under state common law. Vanderwerf v. SmithKlineBeecham Corp., 414 F. Supp. 2d 1023, 1027 and n.2 (D. Kan. 2006) (summarizing Valente but concluding that Act's provision of criminal and administrative penalties for statutory violations without expressly providing private remedies "strongly suggests that Congress did not intend to allow a private cause of action for violation of the statute"). In an opinion issued in the same year as Valente, Menges v. Dupuy Motech, Inc.. 61 F. Supp. 2d, 817, 829 (N.D. Ind. 1999), the court summarily rejected the decision in Cali and cited Valente as authority for allowing a negligence per se claim based on alleged violations of federal regulations related to medical devices.

Wisconsin courts have provided little guidance on this issue. Relying on the same reasoning applied in Valente, plaintiffs cite a few Wisconsin cases in which the state courts have inferred an intent to impose civil liability from a statute's clear expression of concern for safety. In Walker v. Bignell, 100 Wis. 2d 256, 271, 301 N.W.2d 447, 455–56 (1981), the Supreme Court held that even though there was no discernible legislative intent to

impose civil liability in a state statute requiring highway authorities to trim roadside vegetation, "we believe that the requisite intent [to hold municipalities liable for failing to trim] may be supplied by necessary implication from the language of the statute." The court found that statutory language added in 1949 "is such a clear expression of concern for the safety of highway users . . . that we conclude that the municipal bodies so charged are exposed to civil liability for their failure to do that with which they are charged." Id. The state court of appeals has followed Walker's lead in two later cases, inferring legislative intent to create a basis for civil liability from the language and purpose of Wisconsin's safe place statute. Johnson v. Blackburn, 220 Wis. 2d 260, 281, 582 N.W.2d 488, 497 (Ct. App. 1998), aff'd but criticized on other grounds, 227 Wis. 2d 249, 595 N.W.2d 676 (1999); Nordeen v. Hammerlund, 132 Wis. 2d 164, 168–69, 389 N.W.2d 828, 830 (Ct. App. 1986). However, defendant raises a good point when it asserts that these cases can be distinguished on the ground that none of them involved a statute expressly limiting private causes of action.

In support of their specific claim, plaintiffs rely primarily on Kurer v. Parke, Davis & Co., 2004 WI App 74, ¶¶ 1-2, 272 Wis. 2d 390, 393-94, 679 N.W.2d 867, 868, in which the issue was whether a drug manufacturer could be found negligent per se for failing to warn a patient about possible side effects of an oral contraceptive. A Wisconsin court of appeals held that "[i]n Wisconsin, violations of FDA regulations may constitute negligence per se" and noted that "compliance with FDA standards generally will foreclose negligence per se." Id., 2004 WI App 74, at ¶¶ 20 and 22 (citing as authority Lukaszewicz v. Ortho

Pharmaceuticals Corp., 510 F. Supp. 961, 964 (E.D. Wis. 1981), amended, 532 F. Supp. 211 (E.D. Wis. 1981)). See also Schmitz v. Canadian Pacific Railroad Co., 454 F.3d 678, 682 (7th Cir. 2006) (citing Restatement (Second) of Torts § 286) ("In a typical negligence per se case, a violation of a statute can be a basis for liability when the statute is intended to protect against the specific type of harm sustained by the plaintiff."). In Lukaszewicz, 510 F. Supp. at 964-65, the district court found negligence per se under Wisconsin law when a pharmaceutical company failed to warn a patient of the possible side effects of an oral contraceptive, as required under federal regulations. The court did not discuss whether there was a legislative intent to impose civil liability or address the enforcement limitation in § 337(a).

Plaintiffs argue that in Cali, the court did not have the benefit of the Kurer decision that violating FDA regulations can constitute negligence per se and that "there is no reason whatsoever to predict the Wisconsin Supreme Court will reject" the statement in Kurer. Dkt. #72 at 7. They also note that the Supreme Court has held that "a federal court is not free to reject the state rule merely because it has not received the sanction of the highest state court, even though it thinks the rule is unsound in principle or that another is preferable . . . and however much the state rule may have departed from prior decisions of the federal courts." West v. American Telephone & Telegraph Co., 311 U.S. 223, 236-37 (1940).

This case is a close call. Although it is not clear how the Wisconsin Supreme Court would weigh the enforcement limitation in § 337(a) when analyzing the legislative intent to

impose civil liability under state law, the state court of appeals concluded in Kurer, 2004 WI App 74, 272 Wis. 2d at 394, 679 N.W.2d at 867, that a drug manufacturer's violation could constitute negligence per se in Wisconsin. Although I am not convinced that the Wisconsin Court of Appeals fully considered whether the limitation on private rights of action in the Food, Drug and Cosmetics Act showed a legislative intent not to impose civil liability under state law, it is the current statement on the law in Wisconsin. Accordingly, I find that plaintiffs may bring a claim of negligence per se claim under Wisconsin law based on an alleged violation of the medication guide regulations.

ORDER

IT IS ORDERED that defendant Zydus Pharmaceuticals (USA), Inc.'s motion to dismiss the claims of plaintiffs Judy Marvin, Beverly Schultz, Patricia Collins, Robert Elick and Sandra Conley, individually and as next friend of the Estate of Shirley Johns, that defendant was negligent per se in failing to provide medication guides as required by federal law, dkt. #22, is DENIED.

Entered this 23rd day of August, 2016.

BY THE COURT:

/s/

BARBARA B. CRABB
District Judge